REMARKS/ARGUMENTS

This is in response to the Office Action mailed August 26, 2003 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Applicants request and extension of time and enclose the fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

The Examiner has rejected claims 1-22 and 38-40 for obviousness type double patenting in view of US Patent No. 6,051,428. As previously indicated, Applicants will file a terminal disclaimer if such is appropriate upon consideration of claims found to be allowable over the art in this case.

Claim 18 has been amended to change "any of claims 17" to "claim 17". Claims 41-56 have been added. These claims are dependent on claim 4, and contain the same limitations as claims 7 through 22. These claims should be allowable over the art, since no art rejection is made with respect to claims 4-6.

Applicants have amended claim 4 to include the step of "administering transduced tumor cells" which was inadvertently omitted in the last amendment. This is believed to overcome the rejection of claims 4-6 under 35 USC § 112.

The Examiner rejected claims 36 and 37 under 35 USC § 101 as being directed to non-statutory subject matter. The Examiner states that claim 36 would read on tumor cells present in any mammal, including a human, and as such would encompass a human, which is not considered patentable subject mater under § 101. Applicants respectfully disagree.

When a person claims a drug or a mechanical heart, this drug or a device such as a mechanical heart remains within the scope of the patent even when it is used in a human being. Simply because the drug or device is for human use does not render it unpatentable under § 101. The present claims are no different. Applicants are claiming transduced tumor cells, wherever they may be located. They are not claiming human beings. The Examiner has not suggested that tumor cells within the scope of the claims would occur without human intervention so as to be considered products of nature. Thus, the basis for the rejection is in error, and it should be withdrawn.

Applicants further note that the Examiner has misinterpreted applicants prior argument with respect to the Boursnell reference cited as anticipating the claims under 35 USC § 102. The Examiner characterizes Applicants argument as being that "Boursnell does not demonstrate possession of or provide an enabling disclosure of" the invention as now claimed. The

Examiner then proceeds to focus on whether Boursnell is enabling. What Applicants argued, however, is that Boursnell is not properly considered anticipatory because it does not meet the **written description** requirement of § 112.

It is well established that in order to anticipate a claim, the reference relied upon must disclose each and every element of the claimed invention It is also well established that in order to be relied upon as anticipatory, the reference must provide an enabling disclosure of at least one embodiment of the invention as claimed. Further, anticipation cannot be found where selections from among alternatives are required, in order to arrive at the claimed invention.

What has not been addressed before is whether a disclosure that fails to provide a "written description" of an embodiment of the invention, as that phrase in 35 USC § 112, first paragraph has recently been discussed by the Court of Appeals for the Federal Circuit, is sufficient to be considered an anticipatory reference.[1] The issue of whether a reference must provide a "written description" of an invention in order to be anticipatory represents an important understanding within the field of patent law, particularly as it pertains to biotechnology. Already, perhaps in an attempt to respond to the new embellishments of written description, applications are appearing in which a known sequence is transcribed to expressly list every conceivable combination of say 15 bases (i.e., 1-15, 2-16, 3-17 ...). The inventors in such cases have made at most a few of these molecules, and know nothing about the properties of the others. Yet, since there would be no difficulty making a mere 15 bases nucleotide sequence with current technology, such a disclosure does not fail to serve as an anticipatory reference under the enablement requirement. Only by requiring that the reference also provide a written description of the invention can the patent law avoid depriving actual inventors of selected embodiments within such lists from the fruits of their labors, and avoid providing a disincentive for research and development. Stated differently, the test for anticipation has always been whether the reference placed the public in possession of an Applicants' invention. How can a reference accomplish this if it does not even show that the author of the publication had "possession" of the invention. Thus, a "written description" of the invention should be a requirement for any reference that is to be asserted as anticipating a claimed invention.

The Boursnell reference, would not meet the written description standard with respect to the present invention. The sole basis for the assertion of anticipation is the statement bridging columns 7 and 8, that "where nucleotide sequences encoding more than one immunomodulating protein are inserted, they may comprises more than one cytokine or may be a combination of cytokine(s) and accessory molecules." There are no examples of such structures, and no basis to

---

[1] *See, University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997); *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002); *Moba B.V. v. Diamond Automation Inc.*, 66 USPQ2d 1429 (Fed. Cir. 2003).

conclude that Boursnell was in possession of any embodiments or had in fact invented nmucleotide sequences encoding two or more immunomodulatory proteins. The reference does not provide any information about the properties of such species, or whether they provide meaningful utility. This off hand remark in Boursnell is therefore no more than speculative science fiction, which should not form the basis for an assertion of anticipation of claims 1-3 and 7-40. Furthermore, with respect to claims 38-40, applicants are in the process of obtaining a declaration which should be effective to antedate the Boursnell reference with respect to this claims.

For these reasons, upon submission of the Rule 131 declaration, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

Marina T. Larson

Marina T. Larson, Ph.D
Attorney/Agent for Applicant(s)
Reg. No. 32038

(970) 468 6600